PSJ3

Exhibit 432

From: Freitas, Kristen
Sent: Thursday, October 19, 2017 9:20 PM
To: 'Joe Ganley (joe.ganley@mckesson.com)'
Subject: response

This is rough as it is work in process but hopefully it will help. We are going to put this in a finished document soon for others to use. Feel free to pull what you need from this.

The Ensuring Patient Access and Effective Drug Enforcement Act (EPAEDEA) Did Not "Gut" DEA's Authority to Issue Immediate Suspension Orders.

- DEA retains full authority to immediately suspend the DEA registration of a manufacturer, distributor, doctor or pharmacy if there is an "imminent danger to the public health or safety."
- Since 1970, the law has required DEA to show "imminent danger to the public health or safety" before suspending an entity's ability to do business.
- The EPAEDEA clarifies that "public health or safety" expressly includes "abuse of a controlled substance."
- The EPAEDEA defines "imminent danger" as meaning "substantial likelihood of an immediate threat." This is a common-sense, dictionary definition.
- The definition of "imminent danger" in EPAEDEA was negotiated by Senator Hatch with DEA and Department of Justice staff, according to the Senator and the Washington Post.
- The definition of "imminent danger" in EPAEDEA is similar to the standard that DEA used before passage of the law. DEA, however, had never published its standard, leaving the agency free to lower its own requirements, with no notice, if it wished. Including the definition in the statute merely holds DEA accountable to a known standard.
- The definition is appropriate because it requires DEA to link the actions of the specific manufacturer, distributor, doctor or pharmacy to an identifiable public health threat. DEA cannot take the extraordinary step of suspending a registration without a hearing on the sole basis of a generalized harm such as growing overuse of opioid medications.
- Using a similar definition, DEA issued a record number of Immediate Suspension Orders from 2006 to 2010.
- Immediate Suspension Orders are an extraordinary remedy, as they eliminate the registrant's ability to do business even before any hearing on the issues. DEA staff recommend an Immediate Suspension Order, and the DEA Administrator issues the Immediate Suspension Order with no review or input by any judge. The Immediate Suspension Order stops the manufacturer, distributor, pharmacy, or doctor from receiving, storing, manufacturing, distributing, prescribing and/or dispensing controlled substances from the moment DEA issues the Immediate Suspension Order, meaning that it can impact legitimate patients who need medications.
- In the absence of an Immediate Suspension Order, DEA can move forward and revoke a DEA registration through a standard Order to Show Cause hearing procedure or can pressure the registrant to voluntarily surrender its registration.

Corrective Action Plans Allow For Improved Behavior Without Hindering DEA's Enforcement Actions.

- The EPAEDEA allows a DEA-regulated company or person to submit a corrective action plan, identifying ways in which the person will correct its handling of legitimate pharmaceutical products to meet DEA's expectations, before DEA permanently revokes the person's ability to handle those drugs.
- The law does not require DEA to accept a corrective action plan that a DEA registrant submits. DEA is entitled to continue with its hearing to revoke the person's DEA registration, with no delay.
- DEA has rejected every corrective action plan submitted thus far, according to documents DEA has released under FOIA.
- The law explicitly provides that the corrective action plan provisions do not apply to immediate suspension orders, when there is a documented imminent threat to the public health or safety.

- In his review, the DEA Chief Administrative Law Judge, Judge Mulrooney, does not suggest that this new provision seriously hobbles DEA or prevents it from restricting the activities of bad actors. Judge Mulrooney merely suggests that this change was unnecessary because DEA already supports registrants' efforts to reform their activities.
- DEA has said that it prefers to help companies fix their behavior rather than revoke registrations: "DEA does not take the decision to issue an ISO lightly. As with any registrant, DEA's first course of action was not to suspend [the registrant]. Rather, DEA preferred to continue to work with [the registrant] in the hopes that its anti-diversion efforts would become consistently adequate."[1]
- In hearings, DEA Administrative Law Judges such as Judge Mulrooney have routinely refused to consider a person's remedial actions unless the person first admits to ***all*** of DEA's allegations of wrongdoing. The change to the law allows registrants to present a corrective action plan earlier in the process, saving them from the pre-existing dilemma: admit to DEA allegations that are not true, then hope that the judge accepts their remedial actions as adequate, or fight to prove DEA's allegations false, knowing that the judge will not consider their remedial actions.
- Judge Mulrooney says that DEA's standards and requirements "have been static and in place for decades," suggesting that DEA registrants should understand their obligations and that DEA need not allow corrective action plans. Yet the agency has revised, expanded, and redefined its expectations for suspicious order reporting significantly over the past 15 years without changing its regulations. This ongoing policy evolution is the issue that led industry to seek Congressional action. Judge Mulrooney, in his paper, identifies numerous other areas in which DEA has stealthily changed its policies and expectations.
- DEA can address Judge Mulrooney's questions about how to implement these legal changes by revising DEA's regulations that define the processes for administrative hearings. DEA has had such a rulemaking in its regulatory agenda for years.

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[1] Government's brief at 25 in Cardinal v. Holder, DDC 2012

